UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/509,462	07/20/00	BKAILY	G 9555.97USWO

EXAMINER

023552
MERCHANT & GOULD
P O BOX 2903
MINNEAPOLIS MN 55402-0903

HM22/0328

PARTNER, E | PAPER NUMBER 5

1623
DATE MAILED: 03/28/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-27 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-27 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-421-632/40206

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to teach any specific derivatives of the claimed compounds, how to make and use the same. It is well known in the art the alkylation, benzoylation or glycosidation of the hydroxyl groups, chain extension or contraction can greatly alter the activity of the compounds making them inactive. Further, the specification provides evidence that MV8608 and MV8612 possess R-type Ca2+ channel blocking properties but does not provide evidence that the claimed compositions and methods are effective in preventing various diseases or in decreasing proliferation of cancer and tumor cells.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 1 reads on analogs of formula VIIA and VIIB. However, only one structural has been set forth.

It is not clear in claim 1what is encompasses by the terminology "saponin-like derivatives thereof"(claim 1) , "derivative of said saponin-like compound" (claim 2) and "derivatives thereof" (claims 7-9).

The terminology "and pharmaceutically acceptable salts thereof" (claim 1) is an improper markush terminology. Such terminology as "or a pharmaceutically acceptable salt thereof" can be used to overcome the above rejection.

The term "general" (claims 1-2 and 8-9) is superfluous.

Improper markush terminology has been used in claims 8-9. Changing the two term "and" to the term "or" will overcome the above rejection.

It is not clear what is encompassed by the term "preventing" (claim 11, 20 and 22) i.e. it is not clear whether prevention was achieved for a period of days, months, years or whether permanent prevention was achieved.

Claims 11, 14 and 16 are substantial duplicates.

Claims 13, 15 and 17 are substantial duplicates.

Claims 5-7and 10-27 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claims. See MPEP § 608.01(n).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Calixto et al (Br. J. Pharmacol. (1988), 94 1133-1142) or Neves et al (European Journal of Pharmacology, 243 (1993) 213-219).

Each of Calixto et al and Neves et al discloses the claimed compounds and their use in treating diseases. The claimed compounds, compositions and methods are anticipated by each of Calixto et al and Neves et al. In addition, if there are any differences between the claimed compounds, compositions and methods and those disclosed by the references, the differences would appear to be minor in nature and the claimed compounds, compositions and methods, which fall within the scope of the prior art's disclosure, would have been prima facie obvious to a person having ordinary skill in the art at the time the instant invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (703) 308-4616. The examiner can normally be reached on weekdays from 9.30 a.m. to 6.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200